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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/13/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,311

Applicant(s)

Griffith

Examiner

Fox

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/14/02.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-32 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-32 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The Revocation of Power of Attorney and Change of Address of 14 August 2002 has not been entered, since only the first page, without a signature or new address designation, has been received.

Claims 1, 17 and 19 are objected to for their inclusion of blanks (“_____”). It is assumed that the blanks will be replaced with deposit accession numbers.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification on page 34 as to public availability. If the deposit is made under the

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terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

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Claims 6 and 11-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 26-28 are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plants. Claim 6 is broadly drawn to any plant comprising a male sterility trait introgressed into the claimed variety by backcrossing or other traditional means. Claims 11-16, 20, 22-23, 25, 29 and 32 are also broadly drawn to any hybrid plant produced by crossing the exemplified inbred line with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. Claims 17-19, 21, 24, 27, and 30-31 are also broadly drawn to methods of using the transgenic plants, single gene conversion plants, or descendant plants.

No guidance has been provided for the description or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which

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introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny. Guidance has only been provided for a method of using the exemplified inbred cultivar in a process for producing an F1 hybrid.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement

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guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 6 and 11-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 26-28 are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plants. Claim 6 is broadly drawn to any plant comprising a male sterility trait introgressed into the claimed variety by backcrossing or other traditional means. Claims 11-16, 20, 22-23, 25, 29 and 32 are also broadly drawn to any hybrid plant produced by crossing the exemplified inbred line with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. Claims 17-19, 21, 24, 27, and 30-31 are also broadly drawn to methods of using the transgenic plants, single gene conversion plants, or descendant plants.

No guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful

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expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny, or their use.

Hunsperger et al (1996, U.S. Patent 5,523,520), Kraft et al (2000, Theor. Appl. Genet. 101:323-326), and Eshed et al (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger et al teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323). Kraft et al teach that linkage

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disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate the genes responsible for a multitude of non-exemplified traits, to evaluate the ability of these genes to be successfully expressed in various maize genetic backgrounds, or to obtain "single gene conversion" plants which contain a multitude of introgressed traits, but otherwise maintain all of the genetic and physiological and morphological characteristics of the parent plant.

The following amendments would obviate the rejections under 35 USC 112, first paragraph:

Replace claim 6 with claims 33-34 as suggested below to overcome the rejection under 35 USC 112, second paragraph.

In claim 11, insert --F1-- before "hybrid", all occurrences.

Cancel claims 12-32.

Submit new claims 35-44 below (support for said claims can be found in the specification, pages 20-28).

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--New claim 35. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers herbicide resistance.

New claim 36. An herbicide resistant corn plant produced by the method of claim 35.

New claim 37. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers insect resistance.

New claim 38. An insect resistant corn plant produced by the method of claim 37.

New claim 39. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers disease resistance.

New claim 40. A disease resistant corn plant produced by the method of claim 39.

New claim 41. A method of producing a corn plant with decreased phytate content comprising transforming the corn plant of claim 2 with a transgene encoding phytase.

New claim 42. A corn plant with decreased phytate content, produced by the method of claim 41.

New claim 43. A method of producing a corn plant with modified fatty acid or carbohydrate metabolism comprising transforming the corn plant of claim 2 with one or more transgenes encoding a protein selected from the group consisting of stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase, and starch branching enzyme.

New claim 44. A corn plant produced by the method of claim 43.--

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 6, 8 and 20, 23, 25-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite for characterizing the male fertile plant of claim 2 as a male sterile plant. Thus, claim 6 fails to further limit claim 2. Since claim 2 is initially drawn to a plant with defined characteristics and genotypes which exclude the presence of introgressed genes, it is confusing to characterize these plants as comprising additional genes. The cancellation of claim 6, and the submission of the following proposed claims, would obviate this rejection:

--New claim 33. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 2 with a nucleic acid molecule that confers male sterility.

New claim 34. A male-sterile corn plant produced by the method of claim 33.--

Claim 8 is indefinite in its recitation in line 1 of "the...protoplasts" which lacks antecedent basis in claim 6. Amendment of claim 8, line 1 to delete "the" before "cells" would obviate this rejection.

Claims 20, 23, 25 and 29 are indefinite in its recitation of "high", "above average", "good" and "adapted" which are unduly narrative, and so fail to clearly set forth the degree of expression of the claimed traits or the claimed maize plant exhibiting them.

Claim 26, and dependent claims 27-28, are indefinite in their recitation of "plant...of claim 2...transformed so that its genetic material contains one or more transgenes". Since claim 26 is initially drawn to a plant with defined characteristics and genotypes which exclude the presence of

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transgenes, it is confusing to characterize these plants as comprising additional genes. The dependent claims fail to further limit the claims from which they depend.

Claim 31 is confusing in its recitation of "[T]he corn plant breeding program of claim 30" since claim 30 is drawn to a method rather than a breeding program.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by publicly available cultivar A619 as recovered by PVP Database Search (copy of PVP Database Search appended to Cummings).

The claims are broadly drawn to corn inbred line LH321 or plants having all of the morphological characteristics thereof. As stated in the enclosed PVP Database search, publicly available A619 has all of the characteristics of LH321. Since the parent lines of LH321 were not disclosed, and since no other genetic information for LH321 was disclosed, the claimed inbred appears to be identical to A619.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 22-23, 25-26, 29 and 32 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cummings (U.S. 6,455,764 filed January 2001, effectively filed February 2000).

The claims are broadly drawn to a corn plant with at least one “ancestor” being the exemplified inbred Dent maize, wherein the corn plant is obtained by an unspecified number of crosses with an unspecified second maize line, wherein the resultant corn plant exhibits at least two traits including “high yield”, “good stalk lodging resistance”, “above average stalk strength”, “above average test weight”, “above average stay green”, and “adapted to the Central Corn Belt... [or] Western...regions of the United States”, or descendants of transformed corn plants.

Cummings teaches inbred Dent-type maize line WQDS7 developed in Illinois, which has medium green leaves, light sheath pubescence, few marginal waves, green glumes, green-yellow silks, upright ears, white cobs, straight rows, and yellow endosperm (see, e.g., column 12, line 35 through column 13, line 40); wherein the inbred has high yield (see, e.g., column 11, Tables 1 and 2); and wherein the inbred may be transformed (see, e.g., column 15, line 55 through column 16). The maize plant taught by Cummings differs from the claimed maize plant only by its method of manufacture, namely its derivation by outcrossing to the exemplified inbred for a single generation. However, the claimed method of making the maize plant would not confer a unique characteristic to the resultant plant, given the loss of LH321-derived genetic material with every

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generation of outcrossing to a non-LH321 parent, and given the lack of uniqueness of the claimed traits or their degree of expression to LH321.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

January 12, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.